

PHYSICAL SECURITY - GENERAL WAREHOUSE

Management must insure that appropriate physical security measures are taken against the loss of company property and assets. The standards set forth in this section will assist in insuring reasonable protection of the company's assets.

Security of Design and Layout

In all cases of security planning, either for new construction or updating of current facilities, assistance should be requested from the Corporate Compliance Department.

It is suggested that management implement basic physical security designs from a **Security In-Depth Approach**.

In considering the design of a facility, use of all available resources in an efficient manner should be taken into consideration in order to achieve adequate protection for the facility. Emphasis should be placed on the operational requirement of the facility to determine the type and extent of physical security needed.

Protecting a drug warehouse in this day and age is a difficult task. Some of the factors to be taken into consideration when setting up an in-depth security protection system are:

- The exact function to be performed at that location
- The environment - political - economic - legal - terrain
- The vulnerability
- The area (geographic, neighborhood)
- The cost involved
- The possible future changes in the operation

The degree of protection should be predicated on what affect the loss would have on the operation and the relevant importance of the operation to the total business. Additionally, consideration should be given to the degree of susceptibility the operation has to outside threats. These threats are acts or conditions that may result in:

- Disruption of the facility
- Damage, loss or destruction of property
- Personal injury or loss of life
- Compromise of critical information

Threat severity depends on such variables as:

- Type of facility

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- Function performed (distribution of drugs)
- Physical layout and construction
- Geographical location
- Stability of location
- Existing state of law and order
- Protection measures already in affect, if any

Perimeter Barriers

Perimeter barriers may be used to define the physical limits of a facility. They are used generally to restrict, channel or impede access. In addition, they offer two important benefits; create a psychological consideration and have a direct impact on the number of security posts that may be needed. The two major categories of barriers are natural and structural. the one most commonly used is fencing. When practical to do so, all facilities should be fenced. This action will provide a first line of defense against the criminal element.

- Fencing should be of the No. 9 gauge or heavier fabric. The mesh openings should not be larger than two inches. To prevent individuals from going under the fence, a cement apron not less than six inches thick can be installed under the fence. The top of the fence should contain an anti-climb overhang or barbed wire, installed at a 45 degree angle outward, consisting of three strands of barbed wire. In some instances, it may be desirable to employ an additional strand of razor ribbon which is interwoven between the strands of the barbed wire on the top of the fence.
- Gates, entrances and other openings in a perimeter barrier should be limited to the number necessary for efficient and safe operation of the distribution center.
- All fence lines should be cleared areas and be free from obstruction. The area should be cleared of weeds, rubbish, or other material capable of offering cover or assistance to an intruder attempting to climb, cut through, or tunnel under.
- Exterior doors may be an inviting entrance for an intruder because of convenience. The vulnerable points at the door are the frame, hinges, door panels and the lock.
- Doors should be installed so that the hinges are located on the inside. If this is not possible, the hinges should be installed so as to prevent their removal and the exterior pins should not be removable. The hinges that are on the exterior of the doors should be welded, brazed, or otherwise secured.
- Doors should be of metal or solid wood construction.
- Glass exterior doors should be equipped with decorative metal bars or be of the type of glass which resists breakage.
- Rolling overhead doors not controlled or locked by electric power should be protected by slide bolts on the bottom bar on the inside and padlocked when not in use.

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- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a deadbolt lock with at least a one-inch (1") throw. These deadbolt locks should be protected by a case-hardened steel sleeve. This sleeve should cover the deadbolt throw and any other locking mechanism (e.g. electronic strike) on the door.
- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a wide-angle peep-hole. This mechanism will give employees a view of anyone requesting entry into the distribution center from the outside. If there is any doubt about the person's identity, then that person should be informed to report to the front door of the distribution center.
- Employees at the distribution center should not be allowed to park within fifty feet (50') of either the shipping door(s) or the receiving dock. When parking is limited at the distribution center, then it should be a standard rule that employees that work in these areas do not park near their respective work areas.
- There should be absolutely no markings on the distribution center identifying it as a drug warehouse. This includes signs over both the shipping and receiving doors or decals associated with drug associations attached to the glass on the distribution center.
- Utility boxes which are located on the exterior of the distribution center should be equipped with a padlock. If the utility company requests it, they should be issued a key to this box.
- For distribution centers which warrant it, closed circuit television should be installed on the exterior of the distribution center. The monitors for these cameras should be placed in strategic locations throughout the distribution center. The Corporate Compliance Department should be contacted prior to application of closed circuit television cameras.
- Shrubbery, trees and bushes should be trimmed down so that they are not above window level at the distribution center. Any exterior design, such as brickwork, latticework, or an exterior ladder should be removed from the exterior of the distribution center. These elements provide direct access to the roof of the building.

Protective Lighting

This safeguard has considerable value as a deterrent to thieves and vandals or any unauthorized entry. It is an essential element of an **In-Depth Security Program**. Requirements for protective lighting at facilities will depend on the situation and the areas to be protected.

Each situation requires careful study in order to provide the best visibility that is practical for such security functions as prevention of illegal entry, detection of intruders, inspection of vehicles, and illumination for distribution center employees exiting at night.

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- Plan protective lighting to assure adequate illumination to discourage or detect attempts to penetrate an area, and reveal the presence of unauthorized persons within the area.
- Light sources should be located to insure that illumination is directed toward probable courses of intruders.
- Shadowed areas caused by structures near or adjacent to vital areas should be illuminated.
- Design should provide for overlapping light distribution.
- Exterior areas which should receive consideration are fenced perimeters, gate access areas, entrances to the distribution center, and any outside storage areas.
- Emergency power should be included for critical lighting; controls and switches should be locked.
- Lighting in unattended areas can be controlled by time clocks or light sensor equipment.
- The lighting at the distribution center should be checked by a member of the management staff at the distribution center on a routine, periodic basis. Lighting which is not operating properly or is out completely should be repaired immediately.

Locks and Key Control

Locks are the most generally utilized security device. The lock is most commonly used in protecting installations and activities, personnel, classified information, and company property. It should be noted that regardless of their quality or cost, locks should be considered delay devices only and not positive bars to entry. Locks, therefore, must be supplemented, where appropriate, with other security and protection devices and combined into the Security In-Depth Approach.

- The distribution center should have a Lock and Key Control System. It should be a standard practice at the distribution center that the exterior door locks, along with the cage day-gate, vault day-gate, and the combination to the vault be changed on an annual basis, or when an employee having access to the keys to these locks and/or the combination to the vault leaves the company's employ or is transferred to a new location.
- The key to the front door of the distribution center should never be the same as the key to the warehouse. The cleaning crew, alarm company, and the police department should not have a key to the distribution center.
- A Key Log (Form #12) should be maintained or a Key Receipt (Form #13) should be issued for each key distributed at the distribution center. A copy of the key receipt

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goes to 1) the employee; 2) the distribution center manager; and 3) a copy is placed in the employee's personnel file. If an employee is entrusted with a passcard, then that number should also be placed on the key receipt form. Additional Key Receipt forms may be obtained from the Corporate Compliance Department.

- Spare keys to the distribution center, cage, or the combination to the vault should be kept in a secured location at the distribution center. These keys should be kept on the person of the employee entrusted with their care, or they should be kept on a locked desk drawer or small locked cabinet.
- A spare key to the vault should be secured inside the vault in an inconspicuous location. This key should be utilized in case distribution center employees are placed in the vault during the course of a crime.
- Padlocks which are utilized at the distribution center should always be left in the locked position when not in use. The serial numbers on these padlocks should be removed.

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STRUCTURAL SECURITY

Schedule II Controlled Substances (21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations (21 CFR 1301.72(b)) provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

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21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
 - (a) At least one inch in diameter;
 - (b) Set in concrete or installed with lag bolts that are pinned or brazed; and
 - (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
 - (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
 - (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination
- The controlled substance section also provides:
The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

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Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b) provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

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ALARM SYSTEMS

The alarm system at the distribution center should be one which provides telephone line security. Of the phone lines leading into the distribution center are compromised or cut, then this action should result in an immediate alarm at the distribution center. The police should then be notified immediately.

Any opening more than ninety-six square inches on the exterior of the distribution center should be added to the alarm system. These openings include air vents, roof hatches, skylights, etc.

The alarm equipment surrounding the cage and vault should be walk-tested at least once a month. Any equipment failures should be corrected immediately. The **Monthly Alarm Walk Test Report (Form #14)** should be completed and filed or distributed accordingly.

Schedule II Controlled Substances

The vault at the distribution center should be on a separate alarm system. This should be a stand-alone system with the following minimum security requirements:

The walls or perimeter of the vault are equipped with an alarm that includes standby power sources. When unauthorized entry is attempted, the alarm transmits a signal over a supervised alarm transmission circuit directly to a central station protection company; a local or state police agency that has a legal duty to respond; a 24-hour control station operated by the registrant; or such other protection as the administrator may approve.

The door of the vault is equipped with contact switches, and the vault has one of the following:

Complete electrical lacing of the walls, floors and ceilings; sensitive ultrasonic, microwave or passive infrared equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the administrator.

Additional motion detectors should be positioned directly outside and along the approach to the vault. These motion detectors should be able to pick up anyone approaching the vault when the alarm is set.

If necessary, due to local conditions or other problems, hold-up buttons shall be placed at strategic points of entry to the perimeter area of the vault.

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Schedule III, IV, and V Controlled Substances

DEA regulations applicable to the security of Schedule III through V controlled substances state that the cage shall be equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administration may approve.

A cage is protected by motion sensing devices that are positioned or mounted outside (around) and over the cage to detect an intruder prior to an attempt to enter the cage area.

The cage door(s) is equipped with an alarm contact switch.

Alarm Related Security Procedures

The cage and vault alarm system is tested at least **annually** by the alarm contractors. At that time, the alarm contractor is required to perform a **complete on-site inspection**, test and adjustment of the entire alarm system and to replace any components, sensors or wiring that are defective. The alarm contractor confirms, in writing, the results of this inspection, certifying that the system at the time continues to meet the contractual obligations between the company and the alarm contractor and any applicable UL certification standards.

Division management conducts monthly tests of the vault door alarm contact switch as well as any motion sensing or capacitance devices used in conjunction with vault protection. A log is maintained showing the dates of the tests performed, any defects, the date the alarm company was advised of the defect, and the date the problem was corrected.

Such records are maintained on file for 24 months for review by any DEA agent.

Instructions to the alarm company provide that in response to alarm signals, trouble signals, loss of line security or open telephone circuits, the alarm company will promptly respond to the facility, contact the police, if required, and notify division management as designated on a letter of instruction provided by the wholesaler.

Upon notification by the alarm company of the receipt of a signal condition described above, the designated supervisor identifies the caller, confirms that alarm company guards have been dispatched and the police notified, and then proceeds to the premises.

Note: Return call verification to the alarm company should be made any time Cardinal personnel are requested to appear at the premises.

On arrival, the supervisor verifies the presence of the police and/or the alarm company personnel at the site or if such is not the case, continues in his/her vehicle to a safe telephone location where the supervisor calls the police and/or the alarm company to arrange for their coincidental arrival at the premises. In some instances, it may be necessary for the supervisor to proceed to the police station in the vicinity to request a safe escort to the site.

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If only alarm company personnel are present at the supervisor's time of arrival, their identity should be visually confirmed and a request made for the guard to radio his/her office to recall the police. The supervisor and the alarm company should remain outside the premises until the police arrive.

The supervisor should then unlock the entrance door, turn on designated lighting, admit the police and the alarm company personnel, relock the entry door, and then remain in the safest possible area until the police and the alarm company guards have completed their search of the premises.

When entering the premises area, the company supervisor or the alarm company guard should open alarm system protected areas that must be entered in order to search the premises and arrive at the controlled substances vault.

When a search is completed and it has been determined that there is no forced entry or other emergency condition, the company supervisor assists the alarm company guard in resetting the alarms that have been activated and turns off the lights. Both depart the premises through the point of entry in the company of the police and return to their respective stations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

If it is determined that **an actual burglary attack** has taken place, the police officers radio or telephone for additional officers and other assistance.

Additionally, the interior and exterior areas are searched thoroughly for hidden or fleeing intruders; damage, if any, to the vault is repaired; the alarm system is restored and reset; and appropriate surveillance is established to detect any hidden or returning criminal activity. In the event that the burglary is discovered in the absence of police at the scene, the supervisor immediately contacts them to report the crime and request their prompt assistance. In addition, the local DEA office is promptly notified and DEA Form 106 is prepared and filed in accordance with DEA regulations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

Note: Many states require that a report be submitted to the board of pharmacy or other agencies with enforcement jurisdictions.

If the controlled substance vault has been physically penetrated or forced open, the supervisor **must remain at the premises** in charge of the scene until the structure or door is restored to normal or the warehouse reopens on the next business day. This is required despite the restoration of the alarm system since a vulnerability to a hit-and-run burglary would exist until the "physical security" has been restored.

If, for any reason, the alarm system cannot be restored to full normal operation, the supervisor must see to it that the following steps are taken:

- The supervisor remains at the scene and requests assistance, if necessary, from other company supervisors;
- The alarm company guard or service personnel responding to the alarm are requested to stay at the premises until the alarm system has been repaired and restored; and
- If the alarm system still cannot be restored, then the supervisor secures the services of alarm company guards, off-duty police officers, contract security guards or other

appropriate security forces to maintain watch on the premises until security against burglary or robbery can be fully restored.

Note: Under such circumstances, there is a vulnerability relating to the safety of the supervisor and others who may remain on duty at the premises. Precautions that should be taken include locking all perimeter doors and windows, requesting that the police return frequently on a patrol basis, and requiring that the supervisor remain in frequent telephone contact with another supervisor located outside the premises at a safe point. In some instances, commercial telephone circuits may be out of order. In such case, the use of portable radio equipment and cellular phones may be required together with procedures for two-way communication between supervisors and/or the alarm company central station and the police.

- When full security has been restored, division management should review the incident to evaluate the cause and any improper or unsafe actions taken by responding personnel, and revise security procedures where appropriate to provide a more effective and safer response to a similar incident. On the day following the restoration of service, the alarm company is required to have a service supervisor thoroughly test the entire system and certify that the alarm system has in fact been restored to its original condition.

Alarm Related Procedures for Police Connect Alarm System Supervision and Response

Alarm systems connected directly to a police station or municipal communications center that is manned on a 24-hour basis require essentially the same response from the supervisors assigned such duties. The variations in response conditions are as follows:

- On receipt of a phone call from the police, the supervisor contacted requests the name and identification number of the police officer calling. The supervisor then recalls the commercially listed number of the police agency and verifies the authenticity of the call prior to departing the safety of his/her residence.
- On arrival at the warehouse, the supervisor verifies the presence of a police officer or proceeds as previously instructed to again call the police to the scene prior to entering the premises.
- When search and entry of the premises are completed, the supervisor restores the alarm circuits and departs with the police officer.
- In the event that the alarm system cannot be restored, the supervisor contacts the 24-hour telephone number of the alarm company (if available) and requests a service man to respond immediately to the premises to repair, adjust or otherwise restore the alarm system. If feasible, the supervisor should request that the police officers remain at the scene until the alarm company service representative arrives.
- An **Incident Report (Form #15)** should be completed and sent to the Corporate Compliance Department.

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Alarm Systems

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ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access (**Exhibit B**).

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

"The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." (21 CFR 1301.72(d))

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Division management maintains an **Access and Surveillance List (Form #16)** of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a **"Restricted Area" (Exhibit C)** sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

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Access Control

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PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. **Refer to Drug Thefts/Losses within Required Reports to DEA.** The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to 21 CFR 1301.74 (e) upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them.

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

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Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

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Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form -DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of-balance item.
- Run audit report for any out-of-balance item. The **Selected Item Audit Report (Exhibit I)** gives all movement - purchases, returns, sales and inventory adjustments - for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

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Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

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Procedural Security

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SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with 21 CFR 1301.90 and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. **Delivery Vehicle Security Rules (Form #17)** are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

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Shipping

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